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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,024	03/31/2000	Arthur O. Tzianabos	B0801/7169	1627

7590 10/20/2005

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600 Atlantic Avenue  
Boston, MA 02210

EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/540,024

Applicant(s)

TZIANABOS ET AL.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 19, 153, 155-158 and 161 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 19, 153, 155-158 and 161 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Status of claims*

Claims 1, 19, 153, 155-158 and 161 are pending.

The amendment filed 8/12/05, which cancels claims 6-18, 149-152, 154, 159-160 and 162-165 and amends claims 1 and 19 has been entered. Note that claims 2-5 and 20-148 are canceled by applicants' amendment filed 1/24/05.

The following Office action is applied to the pending claims 1, 9, 153, 155-158 and 161.

Please note that the objection(s) and/or rejection(s) not explicitly stated and/or restated below are withdrawn.

### ***Claim Rejections - 35 USC §112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1, 19, 153, 155-158 and 161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is not apparent in “*composed of ... amino moiety and a negative charge*” because said “negative charge” does not conform to said “amino moiety”, as is noted that the negative charge has a general meaning that a surplus of electrons or a lower electric potential. Does the “negative charge” refer to net negative charge of the entire charge moiety, or a negatively

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charged component of a particular chemical moiety? See also claims 19 and 153. The claims depending from claims 1 and 19 are also rejected.

*The applicants' response to the rejection under 35 USC, second paragraph*

On pages 4-5, the response filed 8/12/05 argues that the “negative charge” plainly refers to a negatively charged moiety, and refers the Office to page 20, line 28 to page 21, line 10 of the specification. The applicants’ argument is found to be unpersuasive because the “negative charge”, without further limitation, ambiguously refers to a net native changer of *a moiety* in the recited *charge motif*, or a negatively charged group of a chemical group in said motif (see also the above rejection). The specification (pages 20-21) defines the repeating charge moiety that comprises a positively charged free amino moiety and a negatively charged moiety (page 20, lines 28-30). The specification however does not specifically define the “negative charge” per se in view of said charge motif.

***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The claims 19 and 158 are rejected under 35 U.S.C. 102(b) as being anticipated by Stanley et al. (US Pat. No. 5130417).

In the patent claims 1-2, Stanley et al. discloses an immunogenic protein comprising Ser-Ser-Asp-Lys-Pro-Asp-Asn repeating units. Said protein has molecular weight less than 50 KDa and comprises identical repeating unit, i.e., Ser-Ser-Asp-Lys-Pro-Asp-Asn, which has a positively charged amino moiety (Lys) and a negatively charged moiety (Asp); Lys is separated from Asp by one neutral amino acid residues; wherein the positively charged amino moiety (i.e., Lys  $\epsilon$ -amine group) in said repeating unit is separated from the positively charged amino moiety (i.e., Lys  $\epsilon$ -amine group) in the other (adjacent) repeating unit by a distance of at least 8 amino acids (i.e., 11 residues, see the amino acid sequence depicted in the patent claim 1). The Stanley's protein meets all the structural limitations of the instant polypeptide of claim 19.

Since in Example 2, Stanley et al. teach that the protein comprising the repeating unit is useful for diagnosis of acute invasive disease (see column 11, lines 7-27), the Stanley's product is a pharmaceutical composition. In the Example 1, Stanley et al. further teach that the purified protein is dissolved in a PBS solution, which is considered to a pharmaceutically acceptable carrier. Thus, the above Stanley et al. disclosure and teachings anticipate instant claim 19.

The Stanley's protein is produced by a recombinant synthetic mean (see Example 1), the above Stanley's disclosure and teachings anticipate instant claim 158.

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***Conclusion***

*No claims are allowed.*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

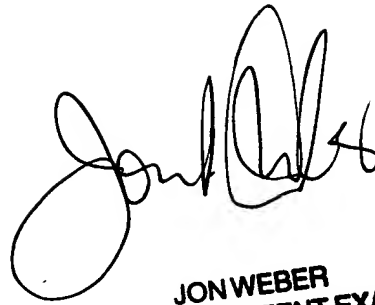
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Samuel Wei Liu, Ph.D.  
Art Unit 1653, Examiner  
October 14, 2005



**JON WEBER**  
**SENIOR PATENT EXAMINER**